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Attorney Docket No. MP/147

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Laguna et al.
Appl. No. : 09/384,900
Filed : August 27, 1999
Title : An Improved Balloon Catheter and
Method of Mounting Same

Group Art Unit : 3763
Examiner : Nguyen, Anh Tuan Tuong

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**BEFORE THE BOARD
OF PATENT APPEALS
AND INTERFERENCES**

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Alexandria, VA 22313-1450, on April 11,
2005.*


Melanee Williams

LETTER OF TRANSMITTAL

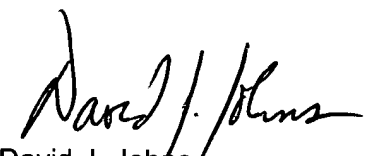
Dear Sir:

Applicants enclose the following papers for filing in the U. S. Patent and Trademark Office
in connection with the above-identified Patent Application:

1. Reply Brief under 37 CFR 1.193(b) (5 pages).

**The Commissioner is hereby authorized and requested to charge all fees due under
section 1.17 during the pendency of this application to our Deposit Account No. 07-1729.**

Respectfully submitted,


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Date: 4/11/05



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REPLY BRIEF UNDER 37 C.F.R. § 1.193(b)

Sir:

This reply brief is filed in response to the Examiner's Answer mailed February 9, 2005, supporting his final rejecting of claims 24-42 in the present application.

Argument

In his Answer the Examiner asserts that the pending claims of the present application are actually presented in product-by-process form and therefore critical limitations in the claims can be ignored since they define structure that exists prior to the final construction of a balloon catheter device. As is explained below, this interpretation of the claims is not justified. The pending claims do not define a product-by-process and this misinterpretation of the claims should be rejected. Reversal of the final rejection and allowance of the pending claims are respectfully requested.

Pending claim 24 defines the present invention as follows:

A sleeve adapted to be mounted on a catheter shaft so as to be formed into an inflatable balloon comprising
the sleeve having a first end, a second end, and a middle section;
wherein prior to being formed into the balloon by mounting on the catheter shaft at least one of the ends is non-distensible while the middle section of the sleeve is distensible.

On its face claim 24 clearly defines “a sleeve” with particular properties. In particular, the sleeve has a distensible middle section and at least one end that is non-distensible. In order to be perfectly clear that they are defining the sleeve itself and not a completed catheter balloon device, applicants have included the limitation that these properties exist in the sleeve “prior to being formed into the balloon.” This limitation is included to clarify the state in which the sleeve should be evaluated for the presence of a non-distensible end and not to define some process step for creating a catheter balloon device.

In the Examiner’s Answer he asserts that the plain limitations of the claim can be ignored because, he alleges, this is actually a product-by-process claim. The Examiner asserts:

Chisum on Patents, Section 8.05, describes a product-by-process claim as one in which the product is defined at least in part in terms of the method or process by which it is made. The construction of claim 24, and specifically, the wherein clause stating “prior to being formed into the balloon by mounting of the catheter shaft” suggests that claim 24 must be considered and interpreted according to the guidelines for product-by-process claims.

Examiner’s Answer, at 4. However, the cited section of Chisum on Patents does not support the Examiner’s position in this regard.

Chisum explains that process words are often used in claims without being interpreted as being process limitations: “Certain apparent ‘process’ words in claims are interpreted as structural limitations when they are used in an adjective non-process sense and adequately define a physical characteristic of the product.” 3 Chisum on Patents §8.05[4]. The Federal Circuit Court of Appeals has likewise held that “That a process limitation appears in a claim does not convert it to a product by process claim.” Fromson v. Advance Offset Plate, Inc., 730 F.2d 1565, 1570, 219 USPQ 1137, 1140 (Fed. Cir. 1983). In the Fromson case the court found that a product claim for a “printing plate” was not converted into a product-by-process claim simply because the claim included the phrase “...resulting from the reaction of aluminum oxide and alkali metal silicate applied to said coating....” Id. Chisum further explains that “Even where terms are amenable to interpretation as a procedure of manufacture, apparent “process” terms should be interpreted as

structural limitations when used in an adjective non-process sense and define a physical characteristic of the apparatus.” 3 Chisum on Patents §8.05[4], at n.6.

The Examiner’s rejection rests upon a fundamental misinterpretation of applicants’ invention. The Examiner presumes that a balloon sleeve cannot be a “product” in and of itself. This is not true. The claims plainly define a “sleeve” and not a completed balloon and, as is explained in the present application, such an inventive sleeve has immense utility over previous sleeve devices. In fact, a primary impetus for the present invention was the need to deliver balloon sleeves to third party manufacturers who would purchase such sleeves and incorporate them into balloon catheter devices. In other words, it has always been applicants’ intention to create a product in the form of a stand-alone balloon sleeve that would be sold and used as such.

In this respect, the present invention is no more a product-by-process than a claim directed to an inventive “tire adapted for mounting on an automobile comprising ...” is defining a process for assembling an automobile. Such a claim is plainly defining a product in the form of a tire and not a completed automobile. Similarly, per in the Fromson case, the language “resulting from the reaction” in a printing plate claim does not render it a process for creating a printing plate.

Based on his misinterpretation of claim 24, the Examiner then asserts that he is free to ignore both the limitation to “sleeve” and the limitation to “prior to being formed into the balloon.” Examiner’s Answer, at 5 (“Accordingly, with respect to claim 24, it is totally irrelevant that at least one of the ends of the sleeve is non-distensible prior to being formed into the balloon” (emphasis in original)). This is necessary to sustain the rejection because each of the references cited by the Examiner describes sleeves that do not have non-distensible ends prior to mounting on a catheter shaft. See Applicants’ Brief, at 3 to 5. This fact is tacitly acknowledged by the Examiner. Examiner’s Answer, at 6-7 (“...the creation in Daneshvar of distensible ends after the formation of the sealed balloon is clearly characteristic of the final product that can be utilized as evidence to evaluate the patentability of claim 24.” (emphasis added)).

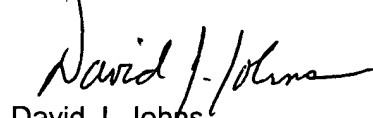
The Examiner has proffered nothing in his Answer to rebut the fact that none of the cited references teaches creating a balloon sleeve that has a distensible middle section and at least one non-distensible end when the sleeves exists in a non-mounted state. Claim 24 should not be interpreted as a product-by-process claim and the Examiner's attempt to misconstrue the claim to ignore clear claim limitations to support his rejection should be rejected. Accordingly, claim 24 defines an inventive sleeve product.

Finally, the Examiner has interjected a new ground for rejection in his Answer. For the first time on pages 7-8 the Examiner has rejected independent claim 24 as being anticipated by U.S. Patent 5,843,116 to Crocker et al. ("Crocker et al. patent"). In fact, the Crocker et al. patent does not anticipate the present invention as claimed since it too describes a structure that achieves a non-distensible end only after it is mounted on a catheter shaft. However, and more importantly, new grounds for rejection are not permitted in the Examiner's Answer (37 C.F.R. §1.193(a)(2) ("An examiner's answer must not include a new ground of rejection...."), MPEP 1208.01). Either the new grounds for rejection should be withdrawn, or prosecution should be reopened to allow full examination of such new grounds prior to appeal. MPEP 1208.02.

Conclusion

For the foregoing reasons and those set forth in Applicants' Appeal Brief, claim 24 of the present application is not anticipated under 35 U.S.C. §102(b) by any of the references of record. Reversal of the Examiner's rejection is respectfully requested.

Respectfully submitted,



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